45. (Amended) A method for detecting the presence of a DNA molecule comprising SEQ ID NO: 115 in a biological sample, the method comprising:

(a) contacting the sample with at least two oligonucleotide primers in a polymerase chain reaction, wherein at least one of the oligonucleotides is specific for [a DNA molecule comprising] SEQ ID NO:224; and

(b) detecting in the sample a DNA sequence that amplifies in the presence of the oligonucleotide primers.

46. (Amended) The method of claim 45, wherein at least one of the oligonucleotide primers comprises at least about 10 contiguous nucleotides of [a DNA molecule comprising] SEQ ID NO:224.

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Following the amendments, claims 23-46 are pending in the application, with claims 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 42 and 45 being in independent format.

Certain pending claims have been amended for purposes of clarity and to more clearly define certain aspects of the applicants' invention. It should also be noted these amendments are not to be construed as acquiescence with respect to the Examiner's rejections and that each of the above amendments is made without prejudice to subsequent prosecution in a related case. Applicants specifically reserve the right to prosecute some or all of the subject matter removed or modified by amendment in one or more related divisional, continuation and/or continuation-in-part applications.

The recitation of oligonucleotides specific for DNA molecules comprising specific SEQ ID NOs. in claims 23-46 has been replaced with the recitation of oligonucleotides specific for the recited SEQ ID NOs. Claims 23, 25, 27, 29, 31 and 33 have been amended to recite methods of the detection of prostate cancer in a biological sample, wherein the biological sample is either blood or semen. Support for this amendment may be found on page 19, lines 3-5

of the specification as originally filed. Claims 30 and 41 have further been amended to correct improper Markush group language.

The pending claims stand rejected under 35 USC §112, first paragraph, as lacking an adequate written description. Specifically, the Examiner states that the specification does not disclose or contemplate the recitation in the claims of "primers specific for complements of the claimed polynucleotides, and detection of the claimed nucleotide sequences in blood or semen."

While the applicants do not acquiesce in the Examiner's objection to the recitation of complements of the specifically recited SEQ ID NOs:, the term complements has been removed from the claims in order to expedite allowance of the amended claims. As noted above, the term "serum" in the claims has been replaced with "semen." Is it urged that support for this aspect of the applicants' invention may be found on page 19, lines 3-5, of the specification as originally filed. The Examiner has further rejected the pending claims under 35 USC §112, first paragraph, as lacking an adequate written description, on the basis that SEQ ID NO:115, 173-175, 177, 223 and 224 are not full-length. This rejection is respectfully traversed.

Applicants note that SEQ ID NO:115, 173-175, 177, 223 and 224 are not recited in claims 23-26 and 35-38, and therefore believe that this rejection should not have been made against claims 23-26 and 35-38.

Following the above amendments, each of the pending claims is drawn to methods of detecting prostate cancer or of detecting the presence of a DNA molecule in a biological sample by contacting the sample with an oligonucleotide primer that is specific for a specifically recited SEQ ID NO. It is not necessary for the specifically recited sequences to be full-length, or to contain an open reading frame, since the claimed methods may be successfully carried out by one of skill in the art without knowledge of the full-length sequence.

It is urged that one of skill in the art, on being provided with the instant specification, would appreciate that the applicants were indeed in possession of the claimed invention at the time the application was filed, and that the rejection of the claims under 35 USC §112, first paragraph, may thus be properly withdrawn.

The pending claims stand rejected under 35 USC §101 as lacking either a specific asserted utility or a well established utility. Specifically, the Examiner states that "the specification lacks utility because the claimed polynucleotides are organ specific" and further

that the "specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids." This rejection is respectfully traversed.

As discussed above, the pending claims are drawn to the use of specifically recited polynucleotides for the detection of prostate cancer and/or specific DNA molecules in a biological sample. As noted by the Examiner, the applicants have clearly shown that the recited polynucleotides are either prostate-specific or are expressed at significantly higher levels in prostate tissue compared to other tissues. Applicants strenuously disagree that "the artisan is invited to elaborate a functional use for the disclosed nucleic acids," since one of skill in the art, on being provided with the instant specification, would clearly appreciate that the recited polynucleotides may be effectively used to detect the presence of prostate cancer.

In response to the Examiner's assertion that the utility of detecting prostate cancer is shared by numerous other unrelated prostate-specific molecules and therefore does not constitute a specific utility, applicants note that the U.S. Patent and Trademark Office Training Materials on the Revised Utility Guidelines states that a specific utility "contrasts with a general utility that would be applicable to the broad class of the invention" and that "a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed." The applicants have clearly disclosed that the recited polynucleotides, on the basis of their prostate-specificity, can be employed in the detection of prostate cancer. Not all polynucleotides can be effectively used in such methods. Indeed, only a very small fraction of known polynucleotides are prostate-specific and can be used to determine the presence of prostate cancer. Such sequences, because of this specificity, are indeed highly sought after as a direct consequence of their diagnostic utility. Reconsideration of the Examiner's rejection under 35 USC §101 is respectfully requested.

The pending claims stand rejected under 35 USC §112, first paragraph, as lacking an enabling disclosure. Specifically, the Examiner states that "since the claimed invention is not supported by a well-established utility and by a clear written description ... one skilled in the art clearly would not know how to use the claimed invention." The Examiner has further objected to the recitation of complements of the specifically recited sequences and of cDNA molecules comprising the specifically recited sequences. Lastly, the Examiner has objected to the

applicants' previous arguments regarding the use of prostate-specific polynucleotides to detect prostate cancer, as not being substantiated with any references.

As discussed above, applicants submit that the claimed methods are indeed supported by a specific and substantial utility and by a clearly written description. Following the above amendments, the recitation of complements and of oligonucleotides specific for cDNA molecules comprising the specifically recited sequences no longer appear in the claims.

With regard to the effectiveness of prostate-specific, as opposed to prostate tumor-specific, sequences in the detection of prostate cancer, although differential overexpression of a sequence in tumor tissue versus normal tissue of the same tissue type is certainly one basis upon which a sequence can have diagnostic utility, the skilled artisan would appreciate that this is by no means the only basis. For example, a prostate-specific sequence can be used in the detection of metastatic prostate cancer cells that have escaped the site of a primary prostate tumor and entered the circulation and/or colonized a distant, non-prostate organ site. In this diagnostic scenario, expression of the sequence in normal prostate tissue is inconsequential.

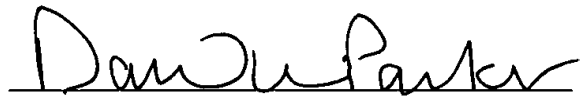
The effectiveness of prostate-specific sequences in the detection of prostate cancer is further underscored by the present wide-spread use of Prostate Specific Antigen (PSA) to diagnose the presence of prostate cancer, as discussed by Stenman et al. *Cancer Biology* (1999) *9*:83-93 and Brawer, *Seminars in Surgical Oncology* (2000) *18*:29-36 (copies enclosed herewith for the Examiner's convenience).

Applicants submit that one of skill in the art to which the present invention pertains, on being provided with the instant specification, would clearly be able to practice the presently claimed methods, and that the rejection of the claims under 35 USC §112, first paragraph, may be properly withdrawn.

Favorable reconsideration and allowance of the amended claims is respectfully requested. Should the Examiner have any further concerns regarding the pending claims, she is respectfully requested to telephone the applicants' representative.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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